Reference number(s)
3801-D

This document applies to the following:

Product	Applies
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Complement Inhibitor Products

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the complement inhibitor products specified in this document. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table 1. Atypical Hemolytic Uremic Syndrome (aHUS), Paroxysmal Nocturnal Hemoglobinuria (PNH) Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Bkemv (eculizumab-aeeb)
Non-preferred	• Soliris (eculizumab) • Ultomiris (ravulizumab-cwvz)

Table 2. Myasthenia Gravis Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Bkemv (eculizumab-aeeb) • Vvygart (efgartigimod alfa) • Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Non-preferred	• Soliris (eculizumab) • Ultomiris (ravulizumab-cwvz)

Table 3. Neuromyelitis Optica Spectrum Disorder (NMOSD) Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Bkemv (eculizumab-aeeb)
Non-preferred	• Soliris (eculizumab)

Step Therapy Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Table 1 Atypical Hemolytic Uremic Syndrome (aHUS), Paroxysmal nocturnal Hemoglobinuria (PNH) Products

Coverage for a non-preferred product is provided when any of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- The request is for Soliris and the member has a documented intolerable adverse event to Bkemv, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
- The request is for Ultomiris and the member has a documented inadequate response or intolerable adverse event with the preferred product.

Table 2 Myasthenia Gravis Products

Coverage for a non-preferred product is provided when any of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- The request is for Soliris and both of the following are met:
    - Member has a documented intolerable adverse event to Bkemv, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
    - Member has a documented inadequate response or intolerable adverse event with either Vyvgart or Vyvgart Hytrulo.
- The request is for Ultomiris and the member has a documented inadequate response or intolerable adverse event with Bkemv, and either Vyvgart or Vyvart Hytrulo.

Table 3 Neuromyelitis Optica Spectrum Disorder (NMOSD) Products

Coverage for a non-preferred product is provided when any of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member has a documented intolerable adverse event to Bkemv, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

1. Bkemv [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2024.
2. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2025.
3. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2024.
4. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; August 2024.
5. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US. Inc.; August 2024.